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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HOLT, ANDRIAE M	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,339	ISELE, UTE	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35,37-63 and 65-75* is/are pending in the application.

4a) Of the above claim(s) *1-29,33-35 and 37-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-32 and 65-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/14/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed April 15, 2010.

Claims 1-35, 37-63 and 65-75 are pending in the application. Claims 1-29, 33-35, and 37-63 are withdrawn from further consideration as being drawn to a nonelected invention from the previous Office Action. Claims 65-75 are newly added. Claims 30-32 and 65-75 will presently be examined to the extent they read on the elected subject matter of record.

Information Disclosure Statement

Receipt of Information Disclosure Statements filed on January 14, 2010 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over van Lengerich (US 6,500,463) in view of Kalbe et al. (CA 2,413,698).

Applicant's Invention

Applicant claims a method for the production of a highly palatable ductile chewable veterinary composition comprising i) feeding the hopper of an extruder with an

effective amount of one or more ingredients that are active against animal pests; meat flavoring; partially gelatinized starch; a softener; and up to about 9% of water, ii) cooling constantly down the mixture of active ingredients and carriers so that the temperature of the extrudate that leaves the tip of the extruder does during the whole extrusion process at no time exceed 40° C, iii) pressing the extrudate through a die that is decisive for the shape of the chewable product, and iv) cutting the extrudate that leaves the extruder into equal pieces.

Determination of the scope of the content of the prior art (MPEP 2141.01)

van Lengerich teaches a process for producing discrete, particulate, shelf-stable encapsulated heat-sensitive components from solids, such as powders, or from solutions or dispersions of the component without the need for pre-drying of the solution or dispersion. van Lengerich teaches that the particulates may be produced at low temperatures without substantial heating or without substantial gelatinization of starch to avoid thermal destruction of the heat-sensitive components, and to avoid substantial expansion. An extrudable, formable, cuttable, mixture or dough may be obtained continuously without the need for removing or evaporating liquid plasticizer prior to extrusion or forming. The processes of the present invention may be used for the continuous production of an edible composition for delivering pharmaceutically or nutritionally active components (col. 4, lines 44-64). van Lengerich teaches a solid encapsulant and/or a liquid encapsulant component which contains an active, sensitive encapsulant dissolved or dispersed in a liquid plasticizer is admixed with a plasticizable

matrix material, which is plasticizable by the liquid plasticizer to encapsulate the active encapsulant at a low temperature and under low shear conditions. van Lengerich teaches a formable mixture is obtained without substantially gelatinizing or cooking the plasticizable matrix material or the substantially non-plasticizable matrix component (col. 7, lines 48-67). van Lengerich teaches the encapsulants and encapsulated products of the present invention may be edible such as pharmaceutically or biologically or nutritionally active components. van Lengerich teaches they may be used for human or animal consumption. The encapsulants and encapsulated products may be suspensions of microorganisms in water, pharmaceutically active compounds, vitamins or minerals in solid (col. 8, lines 50-65). van Lengerich further teaches the inclusion of a matrix component which is substantially non-plasticizable at room temperature, such as non-gelatinized starch, substantially non-gelatinized starch, an inert or bulky material, or carbohydrates which have a lower molecular weight than starches may disrupt, weaken, or soften the glassy matrix formed upon drying the formable mixture (col. 10, lines 14-20). van Lengerich teaches process compatible additional components to facilitate processing, or to improve sensory attributes such as taste, texture, or aroma may be employed, such as flavors (col. 13, lines 63-67).

van Lengerich teaches all of the ingredients may be admixed together at a temperature which does not substantially destroy the encapsulant or substantially gelatinize starch, such as temperatures of less than about 55º C., preferably less than 40º C., most preferably less than about 35º C (mixing ingredients, extrusion process does not exceed 40º C). Mixing or dough temperatures substantially higher than about

50° C are undesirable, because any fat or oil in the formula tends to separate, or the heat sensitive substances to be encapsulated and embedded would be destroyed. In embodiments of the invention, the temperature may be adjusted by external heating, below 50° C, preferably less than 40° C so as to facilitate forming and enable cutting without the material sticking to the cutter (col. 20, lines 4-22). van Lengerich teaches the resulting admixture can be compressed by extrusion through a die into a coherent, dough, capable of being cut into pellets or pieces (col. 20, lines 40-44). Van Lengerich teaches some or all of the dry ingredients may be preblended or dry blended and then admixed with any liquid components such as the plasticizer or a liquid encapsulant component (col. 21, lines 5-19) (pre-mixtures). van Lengerich teaches in example 4, col. 26, lines 64-67-col. 27, lines 1-13, an example of an encapsulated and protected enzyme, batch process. van Lengerich teaches a matrix blend consisting of 29 parts semolina, 6 parts wheat gluten, and 29 parts commercial, non-gelatinized wheat starch may be preblended and mixed with 11 parts of vegetable oil in a mixer for 3 minutes. Then 22 parts of liquid encapsulant (about 70% by weight water) comprising the enzyme phytase and subsequently 3 parts water may be added and mixed for 12 minutes to obtain a blend (mixing ingredients). The blend may then be extruded through extrusion dies having a diameter of about 0.65 mm using a single screw extruder. The blend may be formed into a dough that can be extruded at about 90 bar and at a temperature of about 37° C (temperature not to exceed 40° C, pressing the extrudate through a die that is decisive for the shape). Upon exiting the die, the product may be cut with rotating knives into discrete particles of about 0.5 mm to about 1 mm in

length and air dried for about 30 minutes to obtain shelf-stable pellets which contain encapsulated enzyme (cutting extrudate into equal pieces).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

van Lengerich does not teach the use of meat flavoring in the formulation. It is for this reason Kalbe et al. is added as a secondary reference.

Kalbe et al. teach starch-based extruded shaped articles, characterized in that they comprise specific aromas, bodying agents and pharmaceutical active compounds for animals (page 2, lines 25-27). Kalbe et al. teach the starch-based extruded shaped articles contain poultry liver aroma or meat aroma as aromas (page 2, lines 29-30). Harder et al. teach active compounds which are suitable are, in principle, all active compounds which are suitable for use in veterinary medicine. Especially suitable are the active compounds from the class of the depsipeptides, in particular cyclic depsipeptides. Kalbe et al. teach ancillary substances which are used are: starch, such as, starch from wheat, rice, maize, tapioca, rye, oats and potatoes (page 19, lines 13-14). Kalbe et al. teach materials which are especially suitable for shaping and bodying are cellulose and its derivatives (page 20, lines 1-2). Kalbe et al. teach materials which act as humectants and plasticizers are water, glycerol, propylene glycol, polyethylene glycols and polypropylene glycols (page 20, lines 10-11). Kalbe et al. teach suitable aromas are powdered liver from cattle, poultry, sheep or pigs, preferably poultry and pigs, and other aroma preparations (page 21, lines 13-21). Kalbe et al. teach in example 2, 45% of cornstarch, 10% of sucrose, 10% of liver aroma, Haarmann & Reimer (meat

flavoring), 10% of cellulose acetate powder, 1% of Aerosil and 4% of depsipeptide are homogenized and screened and the mixture is subsequently fed to an extruder via a measuring screw. Accordingly, 5% of water and 15% of glycerol (based on the total mixture) are pumped in via a metering pump. The extrusion temperature is 120° C. The extrudate formed is cut into pieces so that one piece contains the dose for 10 kg of the animal's bodyweight (page 22, lines 11-19).

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of van Lengerich and Kalbe et al. and use meat flavoring in the formulations. van Lengerich teaches a process of preparing pharmaceutical particulates, for humans and animals, at low temperatures without substantial heating or without substantial gelatinization of starch to avoid thermal destruction of the heat-sensitive components. van Lengerich teaches an extrudable mixture is obtained. One skilled in the art at the time the invention was made would have been motivated to use meat flavoring in the formulations because van Lengerich teaches compatible additional components to improve sensory attributes such as taste, texture, or aroma, such as flavors, may be employed in the formulations. As such, the skilled artisan would have been motivated to use the meat flavorings and aromas as taught by Kalbe in the formulations because Kalbe teaches extrudable veterinary formulations with meat flavoring/aromas that are accepted readily by animals. In addition, it is known in the art to use meat flavorings to cover the taste of active agents in veterinary formulations to make the formulations more palatable to the animals.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Response to Arguments

Applicant's arguments filed April 15, 2010 have been fully considered but they are not persuasive. Applicant argues that van Lengerich does not teach or suggest the instantly claimed invention. van Lengerich relates to encapsulation of active ingredients into a matrix to obtain discrete shelf-stable particles that contains a plasticizer, which is mostly water. In response to Applicant's arguments, the components to form the matrix disclosed by the teachings of van Lengerich are the same components disclosed in Applicant's invention. The plasticizable matrix material which is plasticizable at low temperatures by the liquid plasticizer or by the liquid encapsulate component may be a plasticiziable biopolymer such as a modified or pregelatinized starch (pregelatinized starch) (col. 8, lines 66-67-col. 9 lines 1-15). Among the list of active ingredients are many actives that are active against animal pests, pathogens or animal diseases, such as amoxicillin and praziquantel (active ingredients) (cols. 15-17). The plasticizer that is employed is any liquid which enables the formulation of a substantially homogeneous cohesive, plasticized, viscoelastic, formable mixture, dough or crumbly mass. The liquid plasticizer may be any aqueous based composition such as glycerol and polyethylene glycol (softeners) (col. 11, lines 33-50). All of these components are feed into a hopper of an extruder and processed according to the process outlined by the teachings of van Lengerich. van Lengerich specifically teaches that if water is used as a plasticizer,

higher amounts are less desirable, because more drying may be needed to obtain a shelf-stable product. van Lengerich teaches that in the embodiment of the formable mixture or dough the total plasticizer content is generally from about 10% by weight to about 50% by weight. The total content may include water content supplied, any liquid encapsulate component, and an additional plasticizer such as added water, glycerol or a combination for the formation of the dough that is extruded (col. 12, lines 42-62). This indicates that the total weight of the plasticizer, water and glycerol or polyethylene glycol would fall within the range of 10 to 50%. This does not indicate the entire plasticizer is water and that the total water content is higher than 9% as claimed. Applicant does not indicate the percentage of the softener in the formulation; therefore, the skilled artisan would find it obvious that the combination of a softener (glycerol or polyethylene glycol) and water would fall within the metes and bounds of applicant's claims. Therefore, It would have been obvious to the skilled artisan that if these components, active agent, pregelatinized starch, and softeners, were combined to make a dough that can be extruded wherein the whole extrusion process at no time exceeds 40° C, then the end product would be the same.

Applicant argues that van Lengerich discloses hundreds of active ingredients, but none of the active ingredients are capable of being incorporated in a composition at temperatures instantly claimed and that van Lengerich is directed toward human medicines and not to veterinary medicinal compounds confirmed by the fact the van Lengerich does not teach the utilization of meat flavorings. In response to Applicant's arguments, van Lengerich specifically teaches that the products produced are for

human and animal consumption (col. 23, lines 12-21). While van Lengerich discloses a wide range of active ingredients that can be used in the process, many of those active agents are veterinary active compounds, including praziquantel, which Applicant has added as an active ingredient in newly added claims 74 and 75. Applicant does not provide any limitations to independent claim 30 as to what active veterinary compounds can and cannot be used in the formulations. In response to van Lengerich not disclosing the use of meat flavoring, the examiner noted in the previous office action that van Lengerich did not explicitly teach the use of meat flavoring. It is for that reason Kalbe was added as the secondary reference. One skilled in the art at the time the invention was made would have been motivated to use meat flavoring in the formulations because van Lengerich teaches compatible additional components to improve sensory attributes such as taste, texture, or aroma, such as flavors, may be employed in the formulations. As such, the skilled artisan would have been motivated to use the meat flavorings and aromas as taught by Kalbe in the formulations because Kalbe teaches extrudable veterinary formulations with meat flavoring/aromas that are accepted readily by animals. In addition, it is known in the art to use meat flavorings to cover the taste of active agents in veterinary formulations to make the formulations more palatable to the animals.

Applicant argues that Kalbe discloses a manufacture of extruded shaped veterinary articles according to a process used in manufacture of animal food and that the process disclosed in Kalbe cannot be used to produce the products produced by the instantly claimed method. In response to Applicant' argument, Kalbe was added as a

secondary reference to teach the addition of meat flavoring to formulations, not the extrusion process. van Lengerich teaches compatible additional components to improve sensory attributes such as taste, texture, or aroma, such as flavors, may be employed in the formulations. As such, the skilled artisan would have been motivated to use the meat flavorings and aromas as taught by Kalbe in the formulations because Kalbe teaches extrudable veterinary formulations with meat flavoring/aromas that are accepted readily by animals. In addition, it is known in the art to use meat flavorings to cover the taste of active agents in veterinary formulations to make the formulations more palatable to the animals.

Rejections Necessitated by Amendment filed April 15, 2010

Claims 30-32 and 65-75 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Huber et al. (WO 03/030653) in view of Huron et al. (WO 2004/014143).

Applicant's Invention

Applicant claims a method for the production of a highly palatable ductile chewable veterinary composition comprising i) feeding the hopper of an extruder with an effective amount of one or more ingredients that are active against animal pests; meat flavoring; partially gelatinized starch; a softener; and up to about 9% of water, ii) cooling constantly down the mixture of active ingredients and carriers so that the temperature of the extrudate that leaves the tip of the extruder does during the whole extrusion process at no time exceed 40° C, iii) pressing the extrudate through a die that is decisive for the shape of the chewable product, and iv) cutting the extrudate that leaves the extruder

into equal pieces. Applicant claims the active ingredients comprise a macrocyclic lactone selected from the group consisting of avermectins, milbemycins and derivatives thereof.

Determination of the scope of the content of the prior art (MPEP 2141.01)

Huber et al. teach during the extrusion processing starting farinaceous feed ingredients are fed into the elongated barrel of an extruder including at least one elongated, axially rotatable, helically flighted screw with an endmost extrusion die. In preferred forms of the invention, the starting ingredients are first preconditioned prior to passage into the extruder barrel. Generally, during preconditioning the starting mixture is subjected to a temperature of from about 20-98° C. for a period of from about 15-600 seconds (more preferably from about 170-190 seconds). The purpose of preconditioning is to initially moisturize and partially cook the starting material prior to entrance thereof into the extruder barrel. Advantageously, the material leaving the preconditioner has a moisture content of from about 10-60% by weight (page 6, lines 20-31). Huber et al. teach In example 2, an ivermectin-containing dog food was prepared using a Wenger TX-85 twin screw extruder equipped with a Model 16 Wenger DDC preconditioner. The dry ingredients fed to the extruder included (all percentages by weight basis): wheat middlings-18%; meat and bone meal-18%; soybean meal-18%; and corn-46%. In this run, two liquid dispersions were used which contained (all percentages by weight basis): first mixture, propylene glycol-1 lbs and water-11 lbs; second mixture, propylene glycol-48.82%; water-48.82%; Red No. 40 dye-10.86%; and

ivermectin solution-0.50%. In the process, the dry ingredients were fed to the preconditioner where steam and water was added to moisturize and partially precook the mixture. This preconditioned material was then fed to the inlet of the extruder in the usual fashion. The first liquid mixture was added to the outlet end of the preconditioner for passage into the extruder barrel along with the preconditioned material, over a period of about 11 minutes. Thereafter, the colored, ivermectin-containing liquid mixture was added over a period of about 22 minutes. Finally, additional quantities of the first water/propylene glycol liquid mixture were again added, over about 11 minutes (page 10, lines 23-31-page 11, lines 1-16). Huber et al. teach that when the feeds are produced by extrusion they contain respective quantities of protein, fat and starch, together with a relatively minor amount of a desired active or drug (page 4, lines 31-31). Huber et al. teach in most cases, the extruded feed products of the invention should contain from about 5-15% by weight moisture (wet basis), 15-30% by weight protein, more preferably from about 18-25% by weight protein; from about 3-24% by weight fat, more preferably from about 5-20% by weight fat; and from about 5-80% by weight starch, more preferably from about 20-50% by weight starch (page 6, lines 6-10). Huber et al. teach typical dry extruded product has a moisture content of less than about 10% by weight (page 5, line 31). Huber et al. teach a large number of actives can be used in the context of the invention, so long as the actives can withstand feed processing conditions and retain their potency. Among suitable actives are antibiotics, steroids, anti-inflammatory agents, endectocides (e.g., dewormers such as heartworm-preventative drugs) and ectoparasiticides (e.g., drugs effective against fleas and ticks).

Huber et al. teach a number of actives or drugs have been developed for the treatment of heartworm infection, such as the avermectins, which are a class of macrocyclic lactones. Drugs of this class include ivermectin, selamectin, moxidectin, milbemycin oxime and eprinomectin (page 2, lines 9-12).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Huber et al. do not explicitly disclose whole extrusion process at no time exceeds 40° C, the use of a pregelatinized starch, or the various combinations of the active ingredients. It is for this reason Huron is added as a secondary reference.

Huron teaches an edible delivery vehicle or soft chew for the delivery of an additive to an organism (page 9). Huron teaches the starch component comprises about 5 percent to about 60 percent of the soft chew, the sugar component comprises about 5 percent to about 75 percent of the soft chew, and the oil component comprises about 1 percent to about 40 percent of the soft chew. Huron teaches the starch component may also include amylaceous ingredients. The amylaceous ingredients can be gelatinized or cooked before or during the forming step to achieve the desired matrix characteristics. If gelatinized starch is used, it may be possible to prepare the product of the subject invention or perform the process of the subject invention without heating or cooking (page 11). Huron teaches other flavorings for the flavoring component may be used, such as meat (including, but not limited to pork, beef, chicken, fish, poultry, and the like), vegetable, cheese, cheese-bacon and/or artificial flavorings. In preferred embodiments utilizing a flavoring component, the flavoring component is chosen to

enhance the palatability of the composition (page 12). Huron teaches various embodiments further comprise an emulsifier component. A suitable emulsifier component is a glycerin and polyethylene glycol (page 13). Huron teaches an emulsifier component comprises about 0.0 percent to about 40 percent of the soft chew (page 13). Huron teaches exemplary pharmaceuticals include, but are not limited to, ivermectin and praziquantel. Huron teaches exemplary embodiments with more than one pharmaceutical include praziquantel with ivermectin and milbemycin and praziquantel for dogs and cats to control nematodes and tapeworms.

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Huber et al. and Huron and have the whole extrusion process at no time exceed 40° C, use a pregelatinized starch, and use the various combinations of the active ingredients. Huber et al. teach in the extrusion process the temperature ranges from 20-98° C. One skilled in the art at the time the invention was made would have been motivated to use lower temperatures for the extrusion process because Huber et al. teach that the process range starts at 20° C. The skilled artisan would have been motivated to adjust and optimize the temperatures of the extrusion process in a range of 20-40° C based on the active ingredients used in the process in order to maximize the results of the end product.

In reference to the use of a pregelatinized starch, Huber et al. teach that a starch component makes up 5-80% of the formulation. Huber et al. is does not specifically state the type of starch used in the formulation. As such, one skilled in the art at the

time the invention was made would have been motivated to use a pregelatinized starch in the composition, particularly compositions that are extruded at lower temperatures because Huron teaches that pregelatinized starches are good in formulations that are prepared or processed without heating or cooking. As such, the skilled artisan would have been motivated to use the pregelatinized starch in the formulations with a reasonable expectation of success in an extrusion process wherein the temperature of the process does not exceed 40° C.

In reference to the use of the various combinations of active ingredients, one skilled in the art would have been motivated to try different variations and formulations of the macrocyclic lactone active ingredients because the combination of these active ingredients are known in the art. This is evidenced by the teaching of Huron that milbemycin oxime and praziquantel are used in combination to control nematodes and tapeworms in dogs and cats. Therefore, the skilled artisan would have been motivated to combine the various active ingredients with a reasonable expectation of success because these combinations are known in the art to provide more effective treatment and control of animal pests, pathogens, and animal diseases.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

None of the claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on January 14, 2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Andriae M. Holt
Patent Examiner
Art Unit 1616

/John Pak/
Primary Examiner, Art Unit 1616